

## REMARKS

Claims 1-6, 10-25, 33-49 and 51 were pending in the subject application. Claims 10-11 have been cancelled in view of the amendments made to claim 1. Claim 12 has been cancelled based on the objection raised by the Examiner in the last office action, i.e., that the recitation in claim 12 did not change the scope of the claim upon which it depended. Upon entry of the foregoing amendments, claims 1-6, 13-25, 33-49 and 51 will be before the Examiner for consideration.

The specification has been amended to claim priority to U.S. Patent Application 09/807,742 filed April 18, 2001, which is a national stage application under 35 USC § 371 of PCT/US01/06288 filed February 28, 2001, which claims priority under 35 USC § 119 to U. S. Serial No. 60/185,987, filed March 1, 2000, U.S. Serial No. 60/263,473, filed January 23, 2001 and U. S. Serial No. 60/263,688, filed January 23, 2001, and to U.S. Patent Application 09/079,640, filed May 15, 1998, now U.S. Patent No. 7,129,391. In conjunction with this present Amendment, Applicant separately files a Petition for Unintentional Delay in Claiming Priority to these applications.

Claims 1-6, 10-25, 33-49 and 51 are rejected under 35 USC § 112, second paragraph, as they are said to be indefinite. In particular, the office action asserts that reference to sequence identity is indefinite without a reference to a specific sequence identifier. Applicants assert that reference to a sequence identifier is not necessary to avoid indefiniteness since the sequence of IFNa2b is well known, which is even asserted by the Examiner in light of the citation to the Reichert et al. reference as will be addressed below. Reference to a specified percent of identity to IFNa2b can be readily judged and determined by those skilled in the art. Nonetheless, Applicant is prepared to submit a sequence listing pertaining to the well known sequence of IFNa2b. In view of the foregoing remarks, Applicant respectfully requests reconsideration of this rejection.

Claims 1, 3-4, 12-13, 20, 23-25, 33, 35-39 and 41-44 are rejected under 35 USC § 103(a), as being obvious over the McBride et al. reference in view of Reichert et al. Applicant respectfully traverses and otherwise asserts that the amendments to claim 1 obviate this rejection. Claim 1 has been amended to recite that the first and second

flanking sequences comprise a sequence inclusive of a transcriptionally active spacer sequence of the plastid genome. The cited references clearly do not teach the implementation of flanking sequences having this structural feature. This fact is implicitly conceded by the Examiner by the absence of claim 11 under this rejection. Claim 11 recited language pertaining to the flanking sequences including a sequence pertaining to a transcriptionally active spacer sequence. Accordingly, in view of the amendments to claim 1, the cited references do not render claim 1 obvious. Furthermore, the other claims included under this rejection also not rendered obvious, as they are construed to contain the limitations of the base claim from which they depend, claim 1. Applicant respectfully requests reconsideration of this 35 USC § 103(a) rejection.

Furthermore, even without the amendments to claim 1 being considered, Applicant maintains that the cited references would fail to render the claims obvious due to a lack of sufficient deficient disclosure and enablement. It is a well established tenet in patent law that the prior art must enable a claimed invention in order to render it obvious. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989), "Although published subject matter is "prior art" for all that it discloses, in order to render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill to make and use the invention." Applicant points out that a careful examination of the McBride et al. reference reveals that the McBride et al. reference does not sufficiently enable the use and/or plant based expression of interferon. Indeed, interferon is only mentioned once in the entire lengthy document, and that was only the inclusion in a group within a claim of possible things that could be expressed. It is interesting to note that the patent that ultimately issued from the McBride et al. reference (which is a patent publication) does not mention interferon even once. The one mention of interferon in the McBride patent application was removed from the case during examination. The McBride et al. contains no teaching or reference to sequence that encodes an interferon molecule. The McBride et al. reference contains no teaching of how to construct a vector that includes an interferon encoding sequence, nor the successful transformation of an interferon encoding vector. Moreover, the McBride et al. reference is devoid of any teaching of whether an

interferon molecule can be successfully expressed, much less whether the interferon molecule can be properly processed and folded to result in an active protein.

Claims 5, 10-11, 14-17, 19 and 47-49 are rejected under 35 USC 103(a) as being obvious over McBride et al. and Reichert et al., and in view of Daniell. Applicant traverses, and otherwise respectfully asserts that the amendments to claim 1 obviate the grounds for this rejection. Applicant incorporates the remarks concerning the McBride et al. reference made above in rebuttal of the rejection of claim 1. Moreover, the Daniell reference cannot be applied to cure the deficiencies of claim 1, since, in view of the correction of priority, it is disqualified as prior art. As already established above, the McBride et al. and Reichert et al. references teach nothing about implementing a flanking sequence designed for integration into a transcriptionally active spacer region. Thus, for this and other reasons, McBride et al. and Reichert et al. do not render claim 1 obvious. Furthermore, the rejected claims, which ultimately depend from claim 1, are construed to contain all of the limitations of claim 1 and set forth additional distinguishing features. Therefore, it must be concluded that these dependent claims also are not obvious over the McBride et al. and Daniell references. Reconsideration of this 35 USC 103(a) rejection is respectfully requested.

Claims 5-6 and 14-19 are rejected under 35 USC 103(a) as being obvious over McBride et al. in view of Reichert et al., and further in view of Maliga et al. Applicant traverses. Additionally, Applicant respectfully asserts that the amendments to claim 1 obviate the grounds for this rejection. Applicant notes that claim 11 is not included under this rejection for the reason that neither McBride et al., Reichert et al., nor Maliga et al. teach flanking sequences designed for integration into a transcriptionally active spacer region. Applicant further notes that claim 1 has been amended to recite that the first and second flanking sequences comprise a sequence inclusive of a transcriptionally active spacer sequence of the plasmid genome. Thus, as a matter of straightforward logic, the amendments to claim 1 distinguish over the cited references and render claim 1 nonobvious over such cited references. Furthermore, the other rejected claims, which ultimately depend from claim 1, are construed to contain all of the limitations of claim 1 and set forth additional distinguishing features. Therefore, it must be concluded that

these dependent claims also are not obvious over the McBride et al. and Maliga et al. references. Reconsideration of this 35 USC 103(a) rejection is respectfully requested.

Claims 2, 34 and 51 are rejected under 35 USC 103(a) as being obvious over McBride et al. in view of Reichert et al. and in further view of Chandrasegaran. Applicant traverses, and otherwise respectfully asserts that the amendments to claim 1 and 51 obviate the grounds for this rejection. Applicant notes that claim 11 is not included under this rejection for the reason that neither McBride et al., Reichert et al., nor Maliga et al. teach flanking sequences designed for recombination at a transcriptionally active spacer region. Applicant further notes that claim 1 has been amended to recite that the first and second flanking sequences comprise a sequence inclusive of a transcriptionally active spacer sequence of the plastid genome. Claim 51 has been amended similarly. Thus, as a matter of straightforward logic, the amendments to claim 1 distinguish over the cited references and render claims 1 and 51 nonobvious over such cited references. Furthermore, the rejected claims, which ultimately depend from claim 1, are construed to contain all of the limitations of claim 1 and set forth additional distinguishing features. Therefore, it must be concluded that these dependent claims also are not obvious over the McBride et al. Reichert et al. and Chandrasegaran references, either alone or in combination. Reconsideration of this 35 USC 103(a) rejection is respectfully requested.

Claims 40 and 44-45 are rejected under 35 USC 103(a) as being obvious over McBride et al. in view of Reichert et al., and in further view of Conkling et al. and Aycock et al. Applicant traverses. In addition, Applicant respectfully asserts that the amendments to claim 1 obviate the grounds for this rejection. Applicant notes that claim 11 is not included under this rejection for the reason that neither McBride et al., Reichert et al., Conkling et al. nor Aycock et al. teach flanking sequences designed for recombination at a transcriptionally active spacer region. Applicant further notes that claim 1 has been amended to recite that the first and second flanking sequences comprise a sequence inclusive of a transcriptionally active spacer sequence of the plastid genome. Thus, as a matter of straightforward logic, the amendments to claim 1 distinguish over the cited references and render claim 1 nonobvious over such cited

references. Furthermore, the rejected claims, which ultimately depend from claim 1, are construed to contain all of the limitations of claim 1 and set forth additional distinguishing features. Therefore, it must be concluded that these dependent claims also are not obvious over the cited references. Reconsideration of this 35 USC 103(a) rejection is respectfully requested.

Claims 21-22 are rejected under 35 USC 103(a) as being obvious over McBride et al. in view of Reichert et al. and further in view of Rathinasabapathi et al. Applicant traverses. Moreover, Applicant respectfully asserts that the amendments to claim 1 obviate the grounds for this rejection. The Rathinasabapathi reference does not teach flanking sequences designed for recombination at a transcriptionally active spacer region. The rejected claims are construed to contain the limitations of claim 1. As already established, the references do not teach or suggest all of the elements of the rejected claims. Reconsideration of this 35 USC 103(a) rejection is respectfully requested.

Applicants believe that they have fully and adequately addressed all of the rejections of record and urge that the pending claims are in a condition for allowance. Should the Examiner be of the opinion that any other issues remain, Applicant requests that the undersigned be contacted to arrange an interview to address any other outstanding issues.

Respectfully submitted,

/Timothy H. Van Dyke/

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